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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,320	02/08/2000	SHIGETO UCHIYAMA	Q57711	1771

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SUGHRUE MION ZINN
MACPEAK & SEAS
2100 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20037-3202

EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/485,320

Applicant(s)
Uchiyama et al.

Examiner
Irene Marx

Art Unit
1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 25, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1 1/2 20) ☐ Other:

The amendment filed 3/11/02 is acknowledged. Claims 1, 3-7 and 9-12 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the unequivocal designation of strains FERM BP-6436 and FERM BP-6437 as *S. intermedius* or *S. constellatus*.

The ATCC Catalogue adequately demonstrates that strains of each of *S. intermedius* and *S. constellatus* are now reclassified as *S. anginosus*. Thus, there is at least ambiguity as to the proper species classification of the strains of the present invention (See, e.g., page 344).

Therefore, this material raises the issue of new matter and should be deleted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 is

~~are~~ rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is vague and indefinite in the recitation of "a bar, granule, powder, capsule and tablet", as a food composition since claim 9, on which it depends, pertains to a food composition. At least "granule, capsule and tablet" appear to be pharmaceuticals rather than foods. See also claim 12.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishikawa *et al.* taken with Halpin-Dohnalek *et al.* and the ATCC Catalogue of Bacteria.

The claims are drawn to a composition comprising daidzein and a microbial strain which is capable of metabolizing daidzein to equol.

The cited reference discloses a composition comprising soybean milk and a microbial strain of *Streptococcus* which isoflavones such as daidzein and equol. The composition is in a food form and comprises fermented milk and a microorganism which is of the same genus as is found in the claimed composition and which appears to have substantially similar properties of being capable of degrading daidzein to equol. The composition appears to have similar effectiveness because it is disclosed as having biological activity in the prevention of a disease of middle aged to elderly women, such as cancer.

The reference composition differs from the invention as claimed in that it is not provided in a pharmaceutical dosage form. However, Halpin-Dohnalek *et al.* adequately demonstrate that

compositions comprising live microorganisms are provided in capsule or tablet form (See, e.g., col. 4, lines 1-4).

The reference also differs from the claimed invention in that the strain is disclosed as being classified *S. thermophilus* rather than *S. intermedius* or *S. constellatus*. However, the ATCC Catalogue adequately demonstrates that strains of each of *S. intermedius* and *S. constellatus* are now reclassified as *S. anginosus*. Thus, there is at least ambiguity as to the proper classification of the strains of the present invention (See, e.g., page 344). See also the new matter rejection.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the food composition of Isikawa et al. by providing the composition in tablet or capsule form as taught by Halpin-Dohnalek et al. for the expected benefit of providing a *Streptococcus* microorganism, daidzein and other isoflavones in a measured form for the expected benefit of providing a composition that is practical and easy to store and which provides the proper level of active ingredients.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Applicant's arguments as they pertain to the above rejection have been fully considered but they are not deemed to be persuasive.

Applicants' amendment to the recitation of *S. intermedius* and *S. constellatus* in the claims does not overcome the rejection, since the classification of the two strains actually obtained by applicants is at least ambiguous. In addition strains of *S. intermedius* and *S. constellatus* in the art are now reclassified as *S. anginosus*. See, e.g., ATCC Catalogue of Bacteria, page 344). Therefore, it is unclear to what extent the strains differ from *S. thermophilus* in their effects in the composition as claimed.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is of the same genus *Streptococcus* as that claimed, likewise shares the

property of being able to produce equol from daidzein, she has reasonably demonstrated a reasonable likelihood/possibility that the compared strains are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

~~A shortened statutory period for reply to this final action is set to expire THREE~~
MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592, (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.



Irene Marx
Primary Examiner
Art Unit 1651